

[illegible]


1001


TrackWise @ - Admin Scope Details DB: TRWISE


Admin Scope: Admin Activities

Scope, sorted by: Included in Scope (Desc)

	Department	Record Type	Include In Scope
	CAPA - New Jersey	Action Item	<input checked="" type="checkbox"/>
	CAPA - California	Action Item	<input checked="" type="checkbox"/>
	CAPA - Ireland	Action Item	<input checked="" type="checkbox"/>
	Audits - Ireland	Observation	<input type="checkbox"/>
	Audits - California	Audit	<input type="checkbox"/>
	Audits - New Jersey	Observation	<input type="checkbox"/>
	Audits - California	Observation	<input type="checkbox"/>
	CAPA - California	Corrective Action	<input type="checkbox"/>
	CAPA - California	Preventive Action	<input type="checkbox"/>
	Audits - New Jersey	Audit	<input type="checkbox"/>
	CAPA - Ireland	Corrective Action	<input type="checkbox"/>
	CAPA - Ireland	Preventive Action	<input type="checkbox"/>
	Audits - Ireland	Audit	<input type="checkbox"/>
	CAPA - New Jersey	Corrective Action	<input type="checkbox"/>
	CAPA - New Jersey	Preventive Action	<input type="checkbox"/>
	Change Control - California	Request	<input type="checkbox"/>
	Change Control - Ireland	Request	<input type="checkbox"/>
	Change Control - New Jersey	Request	<input type="checkbox"/>
	Complaints - California	Complaint	<input type="checkbox"/>
	Complaints - California	Inquiry	<input type="checkbox"/>
	Complaints - Ireland	Complaint	<input type="checkbox"/>
	Complaints - Ireland	Inquiry	<input type="checkbox"/>

  
 Help

  
 OK

  
 Cancel

1009

1011

1012

1013

FIG. 10

[illegible]

Schedule Details - Monday Friday Every Two Hours DB: TRWISE				
Admin Schedule: Monday Friday Every Two Hours				
Schedule Details:				
Day	Start Time	End Time	Time Interval	
Sunday				
Monday	8:00 AM	5:00 PM	120	
Tuesday	8:00 AM	5:00 PM	120	
Wednesday	8:00 AM	5:00 PM	120	
Thursday	8:00 AM	5:00 PM	120	
Friday	8:00 AM	5:00 PM	120	
Saturday				

Help

Exit

Clear

Copy to All

Edit

FIG. 11



Administration of Setting Selection Values

Admin Activity: Set Priority to Emergency

Set values, sorted by: Field Name (Asc)

Field Name to Set	Field Type	Operation	Set Values
Additional Samples Tested?	Selection		
Affected SOP	Selection		
Assessment Method	Selection		
Assignable Cause	Multi-Selection		
Condition	Selection		
Disposition of Samples	Selection		
Final Disposition	Selection		
Governing SOP	Selection		
Impact	Selection		
Location	Selection		
Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection		
Proposed Disposition	Selection		
Type	Selection		

1301 1303 1305 1307 1306 1309

1302

Help  
Exit  
Save  
Cancel

Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection	Increment	
Product(s)	Multi-Selection	Set	
Proposed Disposition	Selection	Clear	
Type	Selection		

1310 1311

Selection Values DB: TRWISE

Emergency  
Low  
Normal

Help  
Ok  
Cancel

1313

FIG 13

[illegible]

	Field to Set	If Field is Blank, Base Field to Use	+/- Add Value	Time Units	If Field Already Set, Base Field to Use	+/- Add Value	Time Units	Business Days Rule
	Analyst Approval On							
1415	✓ Audit Start Date	Date Created						
	Closed On	Date Created						
	Date Due	Date Due						
	Date Occurred	Date Occurred						
	Date Occurred	Date Opened						
	Director Approval On	Director Approval Or						
	Discovery Date	Discovery Date						
	Discovery Date	Next Audit Date						
	Next Audit Date	QA Approval On						
	QA Approval On	Received Questionnaire						
	Received Questionnaire	Response Due Date						

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FIG. 14

1501

Setting Person Fields

Admin Activity: Set Assigned To

Field to Set	If Field Is Blank, Person to Set	If Field Is Blank, Person Role to Set	If Field Already Set, Person to Set	If Field Already Set, Person Role to Set
2nd Auditor				
Analyst Approval By				
Assigned To		Customer Support		
Closed By		Customer Support		
Contact		Developer		
Director Approval By		Project Leader		
Originator		Project Manager		
Person Notified		Guesty Manager		

1503 1505 1507 1509 1511

1513

1515

Help  
Exit  
Save  
Cancel

Administration of Setting Person Fields

Admin Activity: Set Assigned To

Field to Set	If Field Is Blank, Person to Set	If Field Is Blank, Person Role to Set	If Field Already Set, Person to Set	If Field Already Set, Person Role to Set
2nd Auditor				
Analyst Approval By				
Assigned To			Benson, Harry	
Closed By				
Contact				

1517

Help  
Exit  
Edit

FIG. 15

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	+/- Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
✓ Begin Audit	Perform						
Begin Change Control	Schedule						
Begin Investigation	Perform						
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: "Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only."

1602

1601

1604

1603

1605

1607

1609

1611

Help

Exit

Save

Cancel

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	+/- Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
✓ Begin Audit	Schedule	Current Date/Time	2	Day(s)	Calendar	1614	1615
Begin Change Control							
Begin Investigation							
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: "Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only."

1613

1614

1615

Help

Exit

Save

Cancel

FIG. 16

